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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/604,022

Applicant(s)

COLLINS ET AL.

Examiner

Marcela M. Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 13-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06/04 and 11/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-12 in the reply filed on July 28, 2005 is acknowledged. The traversal is on the ground(s) that both the method groups recite the solid phase synthesis of peptides and the apparatus groups similarly recite an instrument and vessel for carrying out the solid phase synthesis and therefore the searching and examination requirements for all of the claims will be congruent and will not require separate searches and analysis. Examiner has carefully considered these arguments but has not found them persuasive because, as described in the Office Action of July 20, 2005, the methods of Groups I and IV are directed to different inventions which are not connected in design, operation or effect. These methods are independent since they have, e.g., different effects (i.e., synthesizing peptides v. accelerating the synthesis of peptides). In addition, as previously noted, the apparatuses of Groups II and III are different and distinct because they comprise one or more structural features that are mutually exclusive from the structural features of the apparatus of the other group.

As also noted in the previous office action, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Art Unit: 1654

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are presented for examination on the merits.

### ***Claim Objections***

Claims 1-12 are objected to because of the following informalities: In claim 1, step (e) follows step (c). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "acids" in line 3. There is insufficient antecedent basis for this limitation in the claim. Based on the context of the claims, it appears that the word "acids" should actually read "amino acids". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Erdelyi et al. (Synthesis 2002, citation 7 in the IDS of June 7, 2004).

Erdelyi et al. teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

(c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(e) applying microwave energy to accelerate the deprotecting, activating, and coupling cycle. Please note that the instantly claimed functional effects would be inherent to the method taught by Erdelyi et al. (See, e.g., abstract, pages 1594-5).

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (J Org Chem 1992, citation 6 in the IDS of June 7, 2004).

Art Unit: 1654

Yu et al. teach a process for the solid phase synthesis of peptides, which comprises:

- (a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;
- (b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;
- (c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and
- (e) applying microwave energy to accelerate the deprotecting, activating, and coupling cycle. (see, e.g., Scheme I, Figure 1, page 4781, column 2, lines 3-7 and page 4783, column 1, lines 1-10). Please note that the instantly claimed functional effects would be inherent to the method taught by Yu et al.

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1654

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (J Org Chem 1992, citation 6 in the IDS of June 7, 2004) in view of Santagada et al. (Tetrahedron Letters, 2001, citation 4 in the IDS of November 8, 2004) and in view of Greene et al (US 6,288,379, citation 5 in the IDS of June 7, 2004).

Yu et al. beneficially teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

(c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(e) applying microwave energy to accelerate the deprotecting, activating, and coupling cycle. (see, e.g., Scheme I, Figure 1, page 4781, column 2, lines 3-7 and page 4783, column 1, lines 1-10).

Yu et al. do not expressly teach an '*in situ*' method for activating and coupling with the activator, but do beneficially teach a pre-formed ester for activating and coupling (See, e.g., page 4781, column 1, lines 16-23). Also, Yu et al. do not expressly teach monitoring the temperature and moderating the applied power as the reaction progresses and/or pulsing the microwave energy during the reaction in order to control undesired degradation.

Santagada et al. beneficially teach microwave activation and coupling to form dipeptides using an in situ method with, e.g., PyBOP activators (see, e.g., abstract and Table 1).

Greene et al. beneficially teach a multipurpose chemical synthesis microwave process (see, e.g., column 1, lines 13-19, and column 8, lines 20-25) wherein the process involves monitoring the temperature and moderating the applied power based upon the monitored temperature and using pulsed microwave energy to prevent undesired degradation (See, e.g., column 3, lines 40-67, column 4, lines 1-5, column 5, lines 20-58, column 6, lines 10-19, claims and Figures).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such a microwave solid phase peptide synthesis method (e.g., using specifically an '*in situ*' preparation of the activator, monitoring the temperature and adjusting the power accordingly, using pulsed microwave energy and/or proactively cooling the vessel and its contents during the application of microwave energy to prevent undesired degradation) based upon the overall beneficial teachings provided by Yu et al. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Please note that the instantly claimed functional effects would be intrinsic to the method taught by Yu et al.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

**Conclusion**

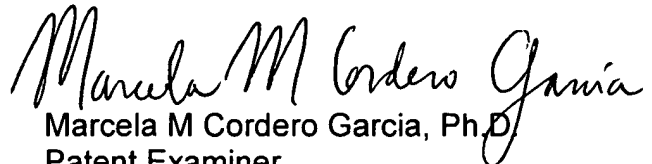
No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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MMCG 09/05

  
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PRIMARY EXAMINER